K080348

AIRSEP®
Industrial & Medical Air Separation Equipment

OCT 09 2008

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# 510(k) Summary

## OxiScan II Oximetry Data Management Software

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|---|---|
| **Submitter:** | **AirSep Corporation** |
| **Address:** | **401 Creekside Drive**<br>**Buffalo, NY 14228**<br>**Tel: (716) 691-0202**<br>**Fax: (716) 691-0707** |
| **Contact Name:** | **Peter Weisenborn**<br>**Vice President – Resources & Regulatory Affairs** |
| **Date Prepared:** | **July 7, 2008** |
| **Trade Name:** | **OxiScan II** |
| **Classification Name:** | **Pulse Oximeter Data Management Software** |
| **Classification:** | **Class II, 21 CFR 870.2700.** |
| **Product Code:** | **DQA** |
| **Predicate Device:** | **OxiScan II Oximetry Data Management Software is substantially equivalent to Nonin Medicals "nVISION" software (K033307)** |
| **Device Description:** | **OxiScan II Oximetry Data Management Software is an accessory for use with compatible pulse oximeters. OxiScan II Oximetry Data Management Software collects and stores patient information containing raw oximetery data captured by a pulse oximeter. This information is transferred by a personal computer to an internet Web server where a report which summarizes and graphically presents the data is prepared. This report is delivered to a Healthcare Professional who then uses it along with other information to determine a course of pulmonary treatment. The report may be retrieved, reviewed, and retransmitted via the OxiScan II Oximetry Data Management Software web site.** |

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Intended Use:

OxiScan II Oximetry Data Management Software (OxiScan II) is a central server based software system that uses a personal computer based application written in Microsoft Dot Net protocol to capture Oximetry data from an oximeter, and then transmit this data, in a secure encrypted file, via internet, to the central server. At the central server the data is used to render a standard report that is then transmitted via fax and/or email to the prescribing physician. The intended use of the report is to provide a physician with information to help determine the best pulmonary treatment.

The OxiScan II Oximetry Data Management Software is intended to collect, report and archive Oximetry trend data to provide information to a medical professional, as a supplemental tool to assist in the timely identification of pulmonary needs.

The OxiScan II Oximetry Data Management Software is intended to (1) transfer Oximetry data from a pulse oximeter to a central server data base in order to maintain unique records per patient and test of this pulse oximetry data, and (2) to generate and archive standard reports drawn from this data. A list of approved oximeters appears in the Capture software.

The OxiScan II Oximetry Data Management Software is not a diagnosis tool. It is a decision management support tool that allows medical personnel to securely and accurately upload and view data related to pulse oximetry and to provide output reports as feedback which may be used by a Heathcare professional to form a patient history.

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| Technological Characteristics: | The OxiScan II Oximetry Data Management Software operates on a personal computer using Windows XP with service pack 2 or later. Both the OxiScan II and the predicate can be used on a personal computer |
| Functional and Safety Testing: | Representative samples of OxiScan II Oximetry Data Management Software were successfully performance tested to verify compliance to appropriate functional characteristics. |

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| **Substantial Equivalence:** | **OxiScan II Oximetry Data Management Software does not have a significant descriptive difference. Based on our review, both the OxiScan II Oximetry Data Management Software and its predicate have similar intended uses, operation methods and performances specifications. Therefore, the OxiScan II Oximetry Data Management Software has been concluded as substantially equivalent to the predicate device.** |
| **Conclusion:** | **OxiScan II Oximetry Data Management Software test results demonstrate functionality, safety and effectiveness, including its substantial equivalence to the predicate device.** |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

Mr. Peter Weisenborn
Vice President – Resources & Regulatory Affairs
AirSep Corporation
401 Creekside Drive
Buffalo, New York 14228-2085

Re: K080348
Trade/Device Name: OxiScan II Oximetry Data Management Software
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 24, 2008
Received: September 29, 2008

Dear Mr. Weisenborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin, MD for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known): K080348

*Device Name:* *OxiScan II Oximetry Data Management Software.*

*Indications For Use:*
OxiScan II Oximetry Data Management Software (OxiScan II) is a central server based software system that uses a personal computer based application written in Microsoft Dot Net protocol to capture oximetry data from an oximeter, and then transmit this data, in a secure encrypted file, via internet, to the central server. At the central server the data is used to render a standard report that is then transmitted via fax and/or email to the prescribing physician. The intended use of the report is to provide a physician with information to help determine the best pulmonary treatment.

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## Compatible Devices And Associated 510[k]'s

| Make/Model | 510K Number |
|---|---|
| **Novametrics 510** | **K924626** |
| **Novametrics 513** | **K032949** |
| **Nonin 8500 Hand Held Pulse Oximeter** | **K893221** |
| **Nonin Model 8500** | **K001930** |
| **Nonin 8500a Pulse Oximeter** | **K945290** |
| **Nonin PalmSat 2500, Hand Held** | **K002690** |
| **Respironics 920M/Plus** | **K004044** |
| **GE Ohmeda TruSat Pulse Oximeter, Ear** | **K040831** |

**Prescription Use** X **AND/OR** **Over-The-Counter Use**_____
**(Part 21CFR 801 Subpart D)** **(21 CFR 801 Subpart C)**

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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